

Atty Dkt 2300-1591 PP01591.101 **PATENT** 

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

GRANDI et al.

Confirmation No.: 4170

Serial No.: 09/914,454

Group Art Unit: Unassigned

Filing Date: February 9, 2000

Examiner: Unassigned

Title: ENHANCEMENT OF BACTERICIDAL ACTIVITY OF NEISSERIA ANTIGENS WITH OLIGONUCLEOTIDES CONTAINING CG MOTIFS

### INFORMATION DISCLOSURE STATEMENT

**Assistant Commissioner for Patents** Washington, D.C. 20231

Sir:

The information listed on the attached PTO-1449 form was cited in an International (PCT) Search Report dated 4 October 2000, in a PCT application corresponding to the above-identified U.S. application. A copy of the Search Report, including an indication of the purported relevance of the cited documents, is enclosed herewith. Copies of the information not previously cited to the Examiner, and a completed PTO-1449 form, are also submitted herewith. The Examiner is requested to make this information of official record in the application.

This Information Disclosure Statement is not to be construed as a representation that: (i) additional information material to the examination of this application does not exist; (ii)

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the information, protocols, results and the like reported by third parties are accurate or enabling; or (iii) the above information constitutes prior art to the subject invention.

Respectfully submitted,

Date: 12/12/02

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### FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) Sheet 1 of 4

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#### **U.S. PATENT DOCUMENTS**

| Exam.<br>Init. | Ref.<br>Desig. | Document No. | Date | Name | Class | Sub<br>Class | Filing<br>Date |
|----------------|----------------|--------------|------|------|-------|--------------|----------------|
|                | A1             |              |      |      |       |              |                |
|                |                |              |      |      |       |              |                |

#### FOREIGN PATENT DOCUMENTS

| Exam.<br>Init. | Ref.<br>Desig. | Document No. | Publication<br>Date            | Country or Patent Office | Class | Sub<br>Class | Trans<br>YES | lation<br>NO |
|----------------|----------------|--------------|--------------------------------|--------------------------|-------|--------------|--------------|--------------|
|                | B1             | WO 96/02555  | 1 February 1996                | PCT                      |       |              |              |              |
|                | B2             | WO 98/16247  | 23 April 1998                  | PCT                      |       |              |              |              |
|                | В3             | WO 98/18810  | 7 May 1998                     | PCT                      |       |              |              |              |
|                | B4             | WO 98/18810  | 7 May 1998 (corrected version) | PCT                      |       |              |              |              |
|                | B5             | WO 98/37919  | 3 September 1998               | PCT                      |       |              |              |              |
|                | B6             | WO 98/40100  | 17 September 1998              | PCT                      |       |              |              |              |
|                | B7             | WO 98/49288  | 5 November 1998                | PCT                      |       |              |              |              |
|                | B8             | WO 98/52581  | 26 November 1998               | PCT                      |       |              |              |              |
|                | В9             | WO 98/55495  | 10 December 1998               | PCT                      |       |              |              |              |

Examiner:

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# FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) Sheet 2 of 4

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| <br>B10 | WO 99/57280 | 11 November 1999 | PCT |  |  |
|---------|-------------|------------------|-----|--|--|
| <br>B11 | WO 99/58683 | 18 November 1999 | PCT |  |  |

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|             | C1          | Ballas et al., "Induction of NK Activity in Murine and Human Cells by CpG Motifs in Oligodeoxynucleotides and Bacterial DNA," <i>J. Immunol.</i> , <u>157</u> :1840-1845 (1996)  |
|             | C2          | Bird, "CpG Islands As Gene Markers In The Vertebrate Nucleus," <i>Trends Genet.</i> , <u>3</u> :342-347 (1987)   |
|             | С3          | Chu et al., "CpG Oligodeoxynucleotides Act As Adjuvants That Switch On T Helper 1 (Th1) Immunity," <i>J. Exp. Med.</i> ,186:1623-1631 (1997)                                     |
|             | C4          | Cowdery et al., "Bacterial DNA Induces NK Cells to Produce IFN-y In Vivo and Increases the Toxicity of Lipopolysaccharides," <i>J. Immunol.</i> , <u>156</u> :4570-4575 (1996)   |
|             | C5          | Davis et al., "CpG DNA Is a Potent Enhancer of Specific Immunity in Mice Immunized with Recombinant Hepatitis B Surface Antigen," <i>J. Immunol</i> , <u>160</u> :870-876 (1998) |
|             | C6          | Halpern et al., "Bacterial DNA Induces Murine Interferon-γ Production by Stimulation of Interleukin-12 and Tumor Necrosis Factor-α," Cell. Immunol, 167:72-78 (1996)             |

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EXAMINER: Initial if citation considered whether or not the citation conforms with MPEP609. Draw a line through the citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



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# FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) Sheet 3 of 4

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|-------------|-------------|---|
|             | C7          | Klinman et al, "CpG motifs present in bacterial DNA rapidly induce lymphocytes to secrete interleukin 6, interleukin 12, and interferon γ," <i>Proc. Natl. Acad. Sci. USA</i> , <u>93</u> :2879-2883 (1996)     |
|             | C8          | Krieg et al., "CpG motifs in bacterial DNA trigger direct B-cell activation," <i>Nature</i> , <u>374</u> :546-549, (1995)   |
|             | C9          | Lipford et al, "CpG-containing synthetic oligonucleotides promote B and Cytotoxic T cell responses to protein antigen: a new class of vaccine adjuvants," <i>Eur. J. Immunol.</i> , <u>27</u> :2340-2344 (1997) |
|             | C10         | Messina et al, "Stimulation of In Vitro Murine Lymphocyte Proliferation by Bacterial DNA," J. Immunol., 147:1759-1764 (1991)  |
|             | C11         | Millan et al., "CpG DNA can induce strong Th1 humoral and cell-mediated immune responses against hepatitis B surface antigen in young mice," <i>Proc. Natl. Acad. Sci</i> , 95:15553-15558 (1998).              |
|             | C12         | Moldoveanu et al, "CpG DNA, a novel immune enhancer for systemic and mucosal immunization with influenza virus," Vaccine, 16:1216-1224 (1988)   |
|             | C13         | Roman et al.,"Immunostimulatory DNA sequences function as T helper-1-promoting adjuvants," <i>Nat. Med.</i> , 3:849-854 (1997)  |
|             | C14         | Stacey et al., "Macrophages Ingest and Are Activated by Bacterial DNA," <i>J. Immunol.</i> , 157:2116-2122 (1996)   |
|             | C15         | Sun et al., "DNA as an Adjuvant: Capacity of Insect DNA and Synthetic Oligodeoxynucleotides to Augment T Cell Responses to Specific Antigen," <i>J. Exp. Med</i> , 187:1145-1150,(1998).                        |

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| Exam. Init. | Ref. Desig. | Description  |
|-------------|-------------|--|
|             | C16         | Weiner et al., "Immunostimulatory oligodeoxynucleotides containing the CpG motif are effective as immune adjuvants in tumor antigen immunization," <i>Proc. Natl. Acad. Sci. USA</i> , 94:10833-10837 (1997)   |
|             | C17         | Yamamoto et al, "In vitro Augmentation of Natural Killer Cell Activity and Production of Interferon-α/β and -γ with Deoxyribonucleic Acid Fraction from <i>Mycobacterium bovis</i> BCG <i>Jpn. J. Cancer Res.</i> , <u>79</u> :866-873 (1988)          |
|             | C18         | Yi et al., "CpG DNA Rescue of Murine B Lymphoma Cells from Anti-IgM-Induced Growth Arrest and Programmed Cell Death Is Associated with Increased Expression of c-myc and bcl-x <sub>L</sub> <sup>1,2</sup> ,"J. Immunol., <u>157</u> :4918-4925 (1996) |
|             | C19         | Yi et al., "CpG Motifs in Bacterial DNA Activate Leukocytes Through the pH-Dependent Generation of Reactive Oxygen Species," <i>J. Immunol.</i> , 160:4755-4761 (1998)   |
| _           | C20         | Yi et al., "CpG Oligodeoxyribonucleotides Rescue Mature Spleen B Cells from Spontaneous Apoptosis and Promote Cell Cycle Entry," <i>J. Immunol.</i> , 160:5898-5906 (1998)   |
|             | C21         | Yi et al., "Rapid Immune Activation by CpG Motifs in Bacterial DNA, J. Immunol., 157:5394-5402 (1996)  |
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